

1 CLAIMS

2 What is claimed is:

3
4 Claim 1. A biopolymer marker selected from the group
5 consisting of sequence ID (K)ALVQQMEQLR(Q),
6 (K)LVPFATELHER(L), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or
7 at least one analyte thereof useful in indicating at least
8 one particular disease state.

9
10 Claim 2. The biopolymer marker of claim 1 wherein
11 said disease state is predictive of Type II diabetes.

12
13 Claim 3. A method for evidencing and categorizing at
14 least one disease state comprising:

15 obtaining a sample from a patient;
16 conducting mass spectrometric analysis on said
17 sample;

18 evidencing and categorizing at least one biopolymer
19 marker sequence or analyte thereof isolated from said
20 sample; and,

21 comparing said at least one isolated biopolymer
22 marker sequence or analyte thereof to the biopolymer
23 marker sequence as set forth in claim 1;

24 wherein correlation of said isolated biopolymer

1 marker and said biopolymer marker sequence as set forth in
2 claim 1 evidences and categorizes said at least one
3 disease state.
4

5 Claim 4. The method of claim 3, wherein said step
6 of evidencing and categorizing is particularly directed to
7 biopolymer markers or analytes thereof linked to at least
8 one risk of disease development of said patient.
9

10 Claim 5. The method of claim 3, wherein said step
11 of evidencing and categorizing is particularly directed to
12 biopolymer markers or analytes thereof related to the
13 existence of a particular disease state.
14

15 Claim 6. The method of claim 3, wherein the sample
16 is an unfractionated body fluid or a tissue sample.
17

18 Claim 7. The method of claim 3, wherein said sample
19 is at least one of the group consisting of blood, blood
20 products, urine, saliva, cerebrospinal fluid, and lymph.
21

22 Claim 8. The method of claim 3, wherein said mass
23 spectrometric analysis is selected from the group
24 consisting of Surface Enhanced Laser Desorption Ionization

1 (SELDI) mass spectrometry (MS), Maldi Qq TOF, MS/MS,
2 TOF-TOF, and ESI-Q-TOF or an ION-TRAP.

3
4 Claim 9. The method of claim 3, wherein said
5 patient is a human.

6
7 Claim 10. A diagnostic assay kit for determining
8 the presence of the biopolymer marker or analyte thereof
9 of claim 1 comprising:

10 at least one biochemical material which is capable of
11 specifically binding with a biomolecule which includes at
12 least said biopolymer marker or analyte thereof, and

13 means for determining binding between said
14 biochemical material and said biomolecule;

15 whereby at least one analysis to determine a presence
16 of a marker, analyte thereof, or a biochemical material
17 specific thereto, is carried out on a sample.

18
19 Claim 11. The diagnostic assay kit of claim 10,
20 wherein said biochemical material or biomolecule is
21 immobilized on a solid support.

1 Claim 12. The diagnostic assay kit of claim 10
2 including:

3 at least one labeled biochemical material.
4

5 Claim 13. The diagnostic assay kit of claim 10,
6 wherein said biochemical material is an antibody.
7

8 Claim 14. The diagnostic assay kit of claim 12,
9 wherein said labeled biochemical material is an antibody.
10

11 Claim 15. The diagnostic assay kit of claim 10,
12 wherein the sample is an unfractionated body fluid or a
13 tissue sample.
14

15 Claim 16. The diagnostic assay kit of claim 10,
16 wherein said sample is at least one of the group
17 consisting of blood, blood products, urine, saliva,
18 cerebrospinal fluid, and lymph.
19

20 Claim 17. The diagnostic assay kit of claim 10,
21 wherein said biochemical material is at least one
22 monoclonal antibody specific therefore.
23

24 Claim 18. A kit for diagnosing, determining risk-

1 assessment, and identifying therapeutic avenues related to
2 a disease state comprising:

3 at least one biochemical material which is capable of
4 specifically binding with a biomolecule which includes at
5 least one biopolymer marker selected from the group
6 consisting of sequence ID (K)ALVQQMEQLR(Q),
7 (K)LVPFATELHER(L) (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at
8 least one analyte thereof related to said disease state;
9 and

10 means for determining binding between said
11 biochemical material and said biomolecule;

12 whereby at least one analysis to determine a presence
13 of a marker, analyte thereof, or a biochemical material
14 specific thereto, is carried out on a sample.

15
16 Claim 19. The kit of claim 18, wherein said
17 biochemical material or biomolecule is immobilized on a
18 solid support.

19
20 Claim 20. The kit of claim 18 including:
21 at least one labeled biochemical material.

22
23 Claim 21. The kit of claim 18, wherein said
24 biochemical material is an antibody.

1 Claim 22. The kit of claim 20, wherein said labeled
2 biochemical material is an antibody.

3
4 Claim 23. The kit of claim 18, wherein the sample is
5 an unfractionated body fluid or a tissue sample.

6
7 Claim 24. The kit of claim 18, wherein said sample
8 is at least one of the group consisting of blood, blood
9 products, urine, saliva, cerebrospinal fluid, and lymph.

10
11 Claim 25. The kit of claim 18, wherein said
12 biochemical material is at least one monoclonal antibody
13 specific therefore.

14
15 Claim 26. The kit of claim 18, wherein said
16 diagnosing, determining risk assessment, and identifying
17 therapeutic avenues is carried out on a single sample.

18
19 Claim 27. The kit of claim 18, wherein said
20 diagnosing, determining risk assessment, and identifying
21 therapeutic avenues is carried out on multiple samples
22 such that at least one analysis is carried out on a first
23 sample and at least another analysis is carried out on a
24 second sample.

1 Claim 28. The kit of claim 27, wherein said first
2 and second samples are obtained at different time periods.
3

4 Claim 29. Polyclonal antibodies produced against a
5 marker sequence ID selected from the group consisting of
6 sequence ID (K)ALVQQMEQLR(Q), (K)LVPFATELHER(L),
7 (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at least one analyte
8 thereof in at least one animal host.
9

10 Claim 30. An antibody that specifically binds a
11 biopolymer including a marker selected from the group
12 consisting of sequence ID (K)ALVQQMEQLR(Q),
13 (K)LVPFATELHER(L), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or at
14 least one analyte thereof.
15

16 Claim 31. The antibody of claim 30 that is a
17 monoclonal antibody.
18

19 Claim 32. The antibody of claim 30 that is a
20 polyclonal antibody.
21

22 Claim 33. A process for identifying therapeutic
23 avenues related to a disease state comprising:

24 conducting an analysis as provided by the kit of

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1 claim 18; and
2 interacting with a biopolymer selected from the group
3 consisting of sequence ID (K)ALVQQMEQLR(Q),
4 (K)LVPFATELHER(L), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or
5 at least one analyte thereof;
6 whereby therapeutic avenues are developed.

7
8 Claim 34. The process for identifying therapeutic
9 avenues related to a disease state in accordance with
10 claim 33, wherein said therapeutic avenues regulate the
11 presence or absence of the biopolymer selected from the
12 group consisting of sequence ID (K)ALVQQMEQLR(Q),
13 (K)LVPFATELHER(L), (R)RVEPYGENFNK(A), (R)LEPYADQLR(T) or
14 at least one analyte thereof.

15
16 Claim 35. The process for identifying therapeutic
17 avenues related to a disease state in accordance with
18 claim 33, wherein said therapeutic avenues developed
19 include at least one avenue selected from a group
20 consisting of 1)utilization and recognition of said
21 biopolymer markers, variants or moieties thereof as direct
22 therapeutic modalities, either alone or in conjunction
23 with an effective amount of a pharmaceutically effective
24 carrier; 2)validation of therapeutic modalities or disease

1 preventative agents as a function of biopolymer marker
2 presence or concentration; 3) treatment or prevention of a
3 disease state by formation of disease intervention
4 modalities; 4) use of biopolymer markers or moieties
5 thereof as a means of elucidating therapeutically viable
6 agents, 5) instigation of a therapeutic immunological
7 response; and 6) synthesis of molecular structures related
8 to said biopolymer markers, moieties or variants thereof
9 which are constructed and arranged to therapeutically
10 intervene in said disease state.

11
12 Claim 36. The process for identifying therapeutic
13 avenues related to a disease state in accordance with
14 claim 35, wherein said treatment or prevention of a
15 disease state by formation of disease intervention
16 modalities is the formation of biopolymer/ligand
17 conjugates which intervene at receptor sites to prevent,
18 delay or reverse a disease process.

19
20 Claim 37. The process for identifying therapeutic
21 avenues related to a disease state in accordance with
22 claim 35, wherein said means of elucidating
23 therapeutically viable agents includes use of a
24 bacteriophage peptide display library or a bacteriophage

1 antibody library.

2

3 Claim 38. A process for regulating a disease state
4 by controlling the presence or absence of a biopolymer
5 selected from the group consisting of sequence ID
6 (K)ALVQQMEQLR(Q), (K)LVPFATELHER(L), (R)RVEPYGENFNK(A),
7 (R)LEPYADQLR(T) or at least one analyte thereof.

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